

REMARKS/ARGUMENTS

The Office Action mailed June 28, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 10-28. Claims 1-9 stand withdrawn.

35 USC 103 Rejection - Van Gerwen et al in View of Nelson et al

In numbered paragraph 8 of the Office Action mailed June 28, 2004, claims 10, 12-18, and 21-28 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the primary Van Gerwen et al reference (WO 97/21094) in view of the secondary Nelson et al reference (U.S. Patent 6,074,827).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The Examiner has noted differences between the primary Van Gerwen et al reference and Applicants' invention defined by claims 10, 12-18, and 21-28. Applicants point out that the primary Van Gerwen et al reference does not have critical elements of the apparatus of Applicants' claims 10, 12-18, and 21-28.

The primary Van Gerwen et al reference does not have Applicants' "beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens." The primary Van Gerwen et al reference does not mention beads.

Also, the primary Van Gerwen et al reference does not have Applicants' "impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies

amplifying the change in impedance.” Since the primary Van Gerwen et al reference does not mention beads, it does not have the feature of the apparatus of Applicants’ claims 10, 12-18, and 21-28 wherein “beads coated with antibodies amplifying the change in impedance.”

The secondary Nelson et al reference does not even show an apparatus including means for determining trapping of pathogens. The secondary Nelson et al reference is directed to, “...an enrichment channel and a main electrophoretic flowpath. The enrichment channel serves to enrich a particular analyte comprising fraction of a liquid sample. The enrichment channel and main electrophoretic flowpath are positioned in the device so that waste fluid from the enrichment channel does not flow through the main electrophoretic channel, but instead flows away from the main electrophoretic flowpath through a discharge outlet. The subject devices may be used in a variety of electrophoretic applications, including clinical assay applications.” (Col. 2, lines 50-60)

There is no teaching for combining the primary Van Gerwen et al reference and the secondary Nelson et al reference. Even if the primary Van Gerwen et al reference and the secondary Nelson et al reference were to be combined, the combination would not produce Applicants’ “Apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel.”

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants’ disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). There is no suggestion or motivation to combine

the primary Van Gerwen et al and the secondary Nelson et al references and Applicants respectfully submit that independent claims, claims 10, 16, and 24 are patentable. Since the other rejected claims depend from the independent claims 10, 16, and 24; claims 10, 12-18, and 21-28 define an invention that is unobvious over the primary Van Gerwen et al reference and unobvious over the secondary Nelson et al reference and unobvious over any legitimate combination of the two references.

35 USC 103 Rejection - Clark et al, Kipling et al, and Nelson et al

In numbered paragraph 9 of the Office Action mailed June 28, 2004, claims 10, 12-13, 16, and 20-26 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the primary Clark et al reference (U.S. Pat. 5,194,133) in view of the secondary Kipling et al Reference (U.S. Pat. 5,374,521) and the tertiary Nelson et al reference (U.S. Patent 6,074,827).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The Examiner has noted differences between the primary Clark et al reference and Applicants' invention defined by claims 10, 12-13, 16, and 20-26. Applicants point out that the primary Clark et al reference does not have critical elements of the apparatus of Applicants' claims 10, 12-13, 16, and 20-26.

The primary Clark et al reference is directed to "sensor device for analysis of a sample fluid, the device comprising a substrate; at least one elongate channel micromachined in a surface of the substrate and containing a material to cause separation of said sample fluid as the fluid passes along the channel; and a plurality of sensing electrode pairs spaced apart along the channel, the electrodes

of each pair being located opposite each other at opposed side walls of the channel.” (Col. 1, lines 45-53, Clark et al Reference)

The primary Clark et al reference does not have Applicants’ “antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies” or “beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens” or “impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance.”

The primary Clark et al reference does not even mention “antibodies” or “beads.” Since the primary Clark et al reference does not mention “antibodies” or “beads,” it does not operate on the principle of the apparatus of Applicants’ claims 10, 12-13, 16, and 20-26 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference and the tertiary Nelson et al reference do not show an apparatus utilizing “beads coated with antibodies.” The secondary Kipling et al reference and the tertiary Nelson et al reference do not operate on the principle of the apparatus of Applicants’ claims 10, 12-13, 16, and 20-26 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference is directed to “a passive process for specifically sensing analyte molecules in a fluid by reflection of bulk acoustic waves from a sensing surface of a bulk acoustic wave quartz sensing device to which analyte molecules bind, said sensing surface having a plurality of receptors for which analyte molecules have an affinity, said process comprises:

i) contacting a fluid in which analyte molecules are suspected with said sensing surface; ii) directing acoustic waves at said sensing surface whereby acoustic waves are reflected from said sensing surface; iii) detecting a change in a characteristic of acoustic waves reflected from said sensing surface due to analyte molecules binding said receptors said change in a reflected acoustic wave characteristic being measured by electrical means detecting values which are related to the amplitude and phase of the reflected acoustic waves.” (Col. 2, lines 6-25, Kipling et al Reference)

The tertiary Nelson et al reference is directed to, “...an enrichment channel and a main electrophoretic flowpath. The enrichment channel serves to enrich a particular analyte comprising fraction of a liquid sample. The enrichment channel and main electrophoretic flowpath are positioned in the device so that waste fluid from the enrichment channel does not flow through the main electrophoretic channel, but instead flows away from the main electrophoretic flowpath through a discharge outlet. The subject devices may be used in a variety of electrophoretic applications, including clinical assay applications.” (Col. 2, lines 50-60, Nelson et al Reference)

There is no teaching for combining the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference. Even if the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference were to be combined, the combination would not produce Applicants’ “Apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel” utilizing “impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance.”

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. In *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). There is no suggestion or motivation to combine the primary Clark et al and the secondary Kipling et al reference and the tertiary Nelson et al reference. Applicants respectfully submit that independent claims, claims 10, 16, and 24 are patentable. Since the other rejected claims depend from the independent claims 10, 16, and 24; claims 10, 12-13, 16, and 20-26 define an invention that is unobvious over the primary Clark et al reference and unobvious over the secondary Kipling et al reference and unobvious over the tertiary Nelson et al reference and unobvious over any legitimate combination of the three references.

35 USC 103 Rejection Clark et al, Kipling et al, Nelson et al and Taylor et al

In numbered paragraph 10 of the Office Action mailed June 27, 2004, claims 11, 14, 17-19, and 27-28 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the primary Clark et al reference (U.S. Pat. 5,194,133) in view of the secondary Kipling et al reference (U.S. Pat. 5,374,521), further in view of the tertiary Nelson et al reference, and further in view of the quaternary Taylor et al (U.S. Pat. 5,001,048) reference.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The Examiner has noted differences between the primary Clark et al reference and Applicants' invention defined by claims 11, 14, 17-19, and 27-28. Applicants point out that the primary Clark et al reference does not have critical elements of the apparatus of Applicants' claims 11, 14, 17-19, and 27-28.

The primary Clark et al reference is directed to "sensor device for analysis of a sample fluid, the device comprising a substrate; at least one elongate channel micromachined in a surface of the substrate and containing a material to cause separation of said sample fluid as the fluid passes along the channel; and a plurality of sensing electrode pairs spaced apart along the channel, the electrodes of each pair being located opposite each other at opposed side walls of the channel." (Col. 1, lines 45-53, Clark et al Reference)

The primary Clark et al reference does not have Applicants' "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies" or "beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens" or "impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

The primary Clark et al reference does not even mention "antibodies" or "beads." Since the primary Clark et al reference does not mention "antibodies" or "beads," it does not operate on the principle of the apparatus of Applicants' claims 11, 14, 17-19, and 27-28 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference, the tertiary Nelson et al reference, and the quaternary Taylor et al reference do not show an apparatus utilizing

"beads coated with antibodies." The secondary Kipling et al reference, the tertiary Nelson et al reference, and the quaternary Taylor et al reference do not operate on the principle of the apparatus of Applicants' claims 11, 14, 17-19, and 27-28 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference is directed to "a passive process for specifically sensing analyte molecules in a fluid by reflection of bulk acoustic waves from a sensing surface of a bulk acoustic wave quartz sensing device to which analyte molecules bind, said sensing surface having a plurality of receptors for which analyte molecules have an affinity, said process comprises: i) contacting a fluid in which analyte molecules are suspected with said sensing surface; ii) directing acoustic waves at said sensing surface whereby acoustic waves are reflected from said sensing surface; iii) detecting a change in a characteristic of acoustic waves reflected from said sensing surface due to analyte molecules binding said receptors said change in a reflected acoustic wave characteristic being measured by electrical means detecting values which are related to the amplitude and phase of the reflected acoustic waves." (Col. 2, lines 6-25, Kipling et al Reference)

The tertiary Nelson et al reference is directed to, "...an enrichment channel and a main electrophoretic flowpath. The enrichment channel serves to enrich a particular analyte comprising fraction of a liquid sample. The enrichment channel and main electrophoretic flowpath are positioned in the device so that waste fluid from the enrichment channel does not flow through the main electrophoretic channel, but instead flows away from the main electrophoretic flowpath through a discharge outlet. The subject devices may be used in a variety of electrophoretic applications, including clinical assay applications." (Col. 2, lines 50-60, Nelson et al Reference)

The quaternary Taylor et al reference is directed to “receptor-based or bioaffinity sensors for the determination of an analyte (or a specific class of analytes) of interest in a sample, and to a method of immobilizing and stabilizing a receptor in the bioaffinity sensor. The receptor-based sensor of the present invention includes a polymeric film in which a receptor selected for its capability to bind an analyte of interest is incorporated.” (Col. 3, lines 42-49, Taylor et al Reference)

There is no teaching for combining the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference and the quaternary Taylor et al reference. Even if the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference and the quaternary Taylor et al reference were to be combined, the combination would not produce Applicants’ “Apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel” utilizing “impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance.”

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants’ disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). There is no suggestion or motivation to combine the primary Clark et al and the secondary Kipling et al reference and the tertiary Nelson et al reference. Applicants respectfully submit that independent claims

10, 16, and 24 are patentable. Since the other rejected claims depend from the independent claims 10, 16, and 24; claims 11, 14, 17-19, and 27-28 define an invention that is unobvious over the primary Clark et al reference and unobvious over the secondary Kipling et al reference and unobvious over the tertiary Nelson et al reference and unobvious over any legitimate combination of the three references.

35 USC 103 Rejection Clark et al, Kipling et al, Nelson et al and Stetter et al

In numbered paragraph 11 of the Office Action mailed June 28, 2004, claim 15 was rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the primary Clark et al reference (U.S. Pat. 5,194,133), in view of the secondary Kipling et al reference (U.S. Pat. 5,374,521), and the tertiary Nelson et al reference, further in view of the quaternary Stetter et al reference (U.S. Pat. 5,567,301).

Applicants have amended claim 15 by amending its parent claim 10. Applicants respectfully submit that claim 10 is patentable over the primary Clark et al reference, the secondary Kipling et al reference, the tertiary Nelson et al reference, and the quaternary Taylor et al reference and any legitimate combination of the references.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The primary Clark et al reference is directed to "sensor device for analysis of a sample fluid, the device comprising a substrate; at least one elongate channel micromachined in a surface of the substrate and containing a material to cause separation of said sample fluid as the fluid passes along the channel; and a plurality of sensing electrode pairs spaced apart along the channel, the electrodes

of each pair being located opposite each other at opposed side walls of the channel.” (Col. 1, lines 45-53, Clark et al Reference)

The primary Clark et al reference does not have critical elements of the apparatus of Applicants’ claim 15. The primary Clark et al reference does not have Applicants’ “antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies” or “beads coated with antibodies located in said space between said electrodes wherein said beads coated with antibodies stick to the pathogens” or “impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance.”

The primary Clark et al reference does not even mention “antibodies” or “beads.” Since the primary Clark et al reference does not mention “antibodies” or “beads,” it does not operate on the principle of the apparatus of Applicants’ claim 15 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference, the tertiary Nelson et al reference, and the quaternary Setter et al reference do not show an apparatus utilizing “beads coated with antibodies.” The secondary Kipling et al reference, the tertiary Nelson et al reference, and the quaternary Setter et al reference do not operate on the principle of the apparatus of Applicants’ claim 15 wherein beads coated with antibodies amplify the change in impedance.

The secondary Kipling et al reference is directed to “a passive process for specifically sensing analyte molecules in a fluid by reflection of bulk acoustic waves from a sensing surface of a bulk acoustic wave quartz sensing device to

which analyte molecules bind, said sensing surface having a plurality of receptors for which analyte molecules have an affinity, said process comprises: i) contacting a fluid in which analyte molecules are suspected with said sensing surface; ii) directing acoustic waves at said sensing surface whereby acoustic waves are reflected from said sensing surface; iii) detecting a change in a characteristic of acoustic waves reflected from said sensing surface due to analyte molecules binding said receptors said change in a reflected acoustic wave characteristic being measured by electrical means detecting values which are related to the amplitude and phase of the reflected acoustic waves." (Col. 2, lines 6-25, Kipling et al Reference)

The tertiary Nelson et al reference is directed to "...an enrichment channel and a main electrophoretic flowpath. The enrichment channel serves to enrich a particular analyte comprising fraction of a liquid sample. The enrichment channel and main electrophoretic flowpath are positioned in the device so that waste fluid from the enrichment channel does not flow through the main electrophoretic channel, but instead flows away from the main electrophoretic flowpath through a discharge outlet. The subject devices may be used in a variety of electrophoretic applications, including clinical assay applications." (Col. 2, lines 50-60, Nelson et al Reference)

The quaternary Setter et al reference is directed to "a biosensor comprising a substrate material, at least one antibody covalently immobilized on the substrate material, and a pair of metal contact electrodes for measuring the impedance of the biosensor." (Abstract, Setter et al Reference)

There is no teaching for combining the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference and the quaternary Setter et al reference. Even if the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Nelson et al reference and

the quaternary Setter et al reference were to be combined, the combination would not produce Applicants' "Apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel" utilizing "impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance."

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). There is no suggestion or motivation to combine the primary Clark et al and the secondary Kipling et al reference and the tertiary Nelson et al reference. Applicants respectfully submit that independent claims, claims 10, 16, and 24 are patentable. Since the other rejected claims depend from the independent claims 10, 16, and 24; claim 15 define an invention that is unobvious over the primary Clark et al reference and unobvious over the secondary Kipling et al reference and unobvious over the tertiary Nelson et al reference and unobvious over any legitimate combination of the three references.

35 USC 103 Rejection – Van Gerwen et al in View of Taylor et al

In numbered paragraph 12 of the Office Action mailed June 28, 2004, claims 11 and 19 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over the primary Van Gerwen et al reference (WO 97/21094) and the secondary Nelson et al reference, in view of the tertiary Taylor et al reference (U.S. Pat. 5,374,521).

Applicants have amended claim 10 and therefore dependent claims 11 and 19. Applicants respectfully submits that amended claim 10 and dependent claims 11 and 19 are patentable over the Van Gerwen et al, Nelson et al, and Taylor et al references and any legitimate combination of the references.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Van Gerwen et al reference and Applicants' invention defined by amended independent claim 10 includes the fact that a number of elements of amended independent claim 10 are not found in the primary Van Gerwen et al reference.

The secondary Nelson et al and tertiary Taylor et al references do not show beads in "an apparatus including means for determining trapping of pathogens carried by a fluid by antibodies deposited in a fluidic channel," or "antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, a fluidic channel having at least one pair of spaced electrodes having surfaces and with a space between said electrodes, said electrodes localized along a length of said fluidic channel, with the electrodes of said at least one pair being located on the same side of said fluidic channel, antibodies immobilized on said surfaces of said spaced electrodes and immobilized in said space between said electrodes wherein said pathogens carried by said fluid attach to said immobilized antibodies, means for producing an electric field across said spaced electrodes, and an impedance sensor for measuring impedance between said spaced electrodes for determining trapping of said pathogens by measuring change in

impedance between said pair of spaced electrodes with said beads coated with antibodies amplifying the change in impedance.”

Further, there is no suggestion or motivation to combine the primary Van Gerwen et al reference, the Nelson et al reference, and the Taylor et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants’ disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Since there is no suggestion or motivation to combine the Van Gerwen et al, Nelson et al, and Taylor et al references to produce Applicants’ invention, a 35 USC §103(a) rejection of Applicants’ amended independent claim 10 would not be appropriate. Applicants respectfully submit that the independent claim 10 is patentable and since claims 11 and 19 depend from independent claim 10, claims 11 and 19 presented for examination are patentable.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated June 28, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Eddie E. Scott", is written over a horizontal line.

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